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APPLICANT:	Petr Jakovlevich Gaponyuk et al.	)
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TITLE:	ANTIVIRAL AGENT IN THE FORM OF NOSE DROPS	

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CLEAN VERSION OF AMENDED SPECIFICATION

Title

ANTIVIRAL NASAL DROPS COMPRISING RECOMBINANT INTERFERON, A BIOCOMPATIBLE POLYMER, AND AN ANTIOXIDANT

Page 1, Paragraph 4

In Russia, natural human interferons derived from leukocytes have been widely used for the treatment and prevention of influenza and acute viral respiratory infections (AVRI) since the late 1960s. This interferon was manufactured from expensive donor blood leukocyte preparations (RU, Patent 2033180, Cl. A 61 K 38/21, 1995. SU, Inventor's Certificate 297296, Cl. A 61 K 36/21, 1977. RU, patent 2108804, Cl. A 61 K 38/21, 1996).

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To solve this problem, we developed an antiviral drug (nasal drops) containing a liquid interferon preparation (a genetically engineered alpha, beta or gamma interferon with viscosity of (1.1 – 30.0) * 10 Pascal·second). The antiviral drug contains a biocompatible polymer, antioxidant, and buffer mixture with the following contents of ingredients per ml buffer mixture:

Genetically engineered interferon	1000 – 50,000 IU
Biocompatible polymer	0.005 – 0.714 g
Antioxidant	0.0001 – 0.0008 g

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TRILON B® (disodium salt of ethylenediaminetetraacetic acid ("EDTA")) is used as an antioxidant, and polyvinylpyrrolidone and/or polyethylene oxide is used as a biocompatible polymer. The drug described here contains polyvinylpyrrolidone and polyethylene oxide at a ratio of 1:1 – 50.

Page 4, Paragraph 1

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Variant 1. The technology of manufactured this drug (nasal drops) is the same for all variants described below. Prepare solutions of the following ingredients in separate containers: 50% polyethylene oxide, 6% polyvinylpyrrolidone and 10% aqueous TRILON B® (disodium salt of EDTA). Filter the solutions. Use phosphate-buffered saline as a solvent. Add these solutions to a manufacturing vessel in the specified sequence, and sterilize. Then add genetically engineered interferon. Mix the ingredients. Dispense the solution into appropriate containers, hermetically seal and label.

Suggested composition of the antiviral drug:

Each milliliter of the buffer mixture contains:

Genetically engineered interferon beta	500,000 IU
Polyvinylpyrrolidone	0.014 g
Polyethylene oxide	0.7 g
TRILON B® (disodium salt of EDTA)	0.0008 g
Viscosity of solution	30.0*10 Pascal·second

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Variant 2. Proceed as described under Variant 1.

Suggested composition of the antiviral drug:

Each milliliter of the buffer mixture contains:

Genetically engineered interferon alpha	10,000 IU
Polyvinylpyrrolidone	0.01 g
Polyethylene oxide	0.1 g
TRILON B® (disodium salt of EDTA)	0.0004 g
Viscosity of solution	3.0*10 Pascal·second

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Page 5, Paragraphs 1-2

Suggested composition of the antiviral drug:

Each milliliter of the buffer mixture contains:

Genetically engineered interferon gamma	1,000 IU
Polyvinylpyrrolidone	0.05 g
TRILON B® (disodium salt of EDTA)	0.0001 g
Viscosity of solution	1.1*10 Pascal·second

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FEASIBILITY OF INDUSTRIAL-SCALE MANUFACTURE

The antiviral drug (nasal drops) obtained as described in the previous section has the appearance of a clear liquid whose viscosity differs between variants. Laboratory tests performed on cultured animal cells showed that the drug is not toxic and fully conserves its antiviral activity.